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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,427	01/12/2004	Lee Bolduc	203-2626 DIV CON VIII (24)	9695
7590 Mark Farber, Esq. U.S. Surgical, A Division of Tyco Healthcare Group, LP 150 Glover Avenue Norwalk, CT 06856			EXAMINER YABUT, DIANE D	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 04/10/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/755,427	<b>Applicant(s)</b> BOLDUC ET AL.	
	<b>Examiner</b> DIANE YABUT	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02/05/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This action is in response to applicant's amendment received on 02/05/2009.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

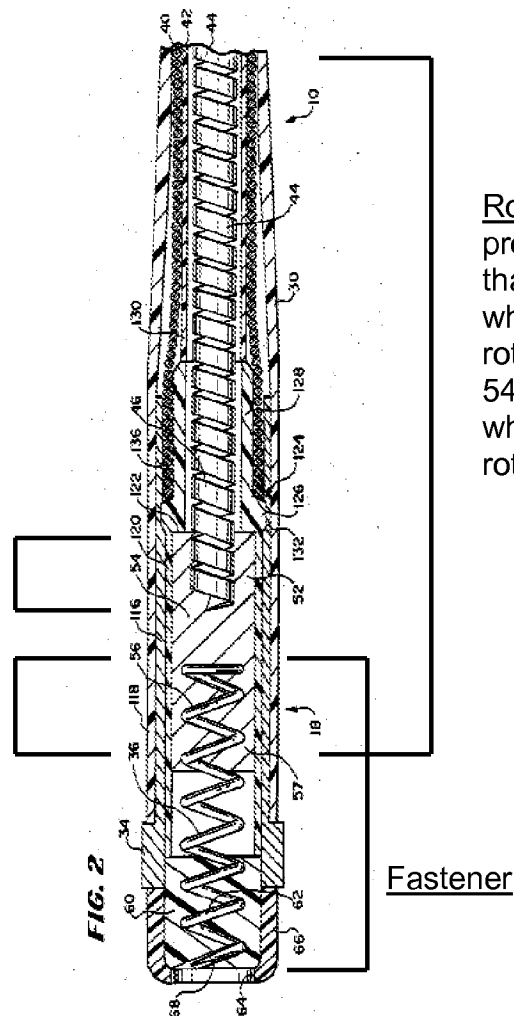
2. Claims 1, 4-6, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by **Miller** (U.S. Patent No. **4,628,943**).

Claims 1, 4-6 and 19: Miller discloses an applicator comprising a distal portion having an elongate outer tube **30**, a connecting end and a terminal end, a proximal portion having a handle and an actuator **22**, the proximal portion being attached to the connecting end of the distal portion, and a rotator **44** cooperating with the actuator, the rotator including a longitudinal groove extending along at least a portion thereof (within the distal end **54** of rotator), the groove configured to receive a portion of a fastener **36**, wherein the rotator resides within and extends substantially the length of the outer tube such that actuation of the actuator rotates and translates the fastener relative to the outer tube while the rotator remains longitudinally or axially stationary with respect to the outer tube (Figures 1-3; col. 5, line 57 to col. 6, line 22). The applicator has a thread form **62** contained in an interior of the terminal end adapted to engage a plurality of fasteners and being an interlock spring fixedly retained in the interior of the terminal

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end, wherein "spring" is taken to mean an "actuating force." This may also be considered as a nose piece **60** that has structures projecting perpendicularly toward a longitudinal axis of the outer tube and adapted to engage a plurality of fasteners. The proximal and distal portions

Longitudinal grooves are within distal end 54 of rotator which engage with the proximal end 44 of rotator and proximal end of fastener 62



Rotator has a proximal end 44 that is rotated, which in turn rotates a distal end 54 of the rotator, which ultimately rotates fastener 62

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller** (U.S. Patent No. **4,628,943**) in view of **Smith et al.** (U.S. Patent No. **4,596,350**).

Claims 2-3: Miller discloses the claimed device, except for a lock/clip indicator for engaging a plurality of fasteners which is configured to prevent actuation of the actuator upon discharge of the plurality of fasteners from the applicator, and a load spring for applying longitudinal forces against the lock/clip indicator.

Smith et al. teach a lock/clip indicator **51** for engaging a plurality of fasteners which is configured to prevent actuation of the actuator upon discharge of the plurality of fasteners from the applicator, and a load spring **20** for applying longitudinal forces against the lock/clip indicator (col. 9, lines 35-52). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a lock/clip indicator and load spring, as taught by Smith et al., to Miller since it was known in the art that lock/clip indicators with spring mechanisms prevent undesirable forward advancement of fasteners.

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5. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller** (U.S. Patent No. **4,628,943**) in view of **Green et al.** (U.S. Patent No. **5,100,420**).

Claims 7-8: Miller discloses the claimed device, except for the distal portion and the proximal portion being releasably secured together and the distal portion being disposable and the proximal portion being reusable.

Green et al. teach a distal portion being disposable and the proximal portion being reusable (col. 10, lines 47-51). It would have been obvious to one of ordinary skill in the art to provide a disposable distal portion and a reusable proximal portion, as taught by Green et al., to McPherson et al. since it was known in the art that disposable distal portions of medical devices is a solution to time-consuming sanitation of the distal ends prior to being introduced into the body.

6. Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller** (U.S. Patent No. **4,628,943**) in view of **Pratt et al.** (U.S. Patent No. **5,607,436**).

Claims 9 and 14: Miller discloses the claimed device, except for a lever with a first end, a midsection, and a second end, a lead screw, and a nut driver.

Pratt et al. teach a lever **14** having a first end, a midsection, and a second end, the lever pivotally attached about a midpoint to the handle, the first end of the lever for gripping by hand, a lead screw **54** rotatably attached to interior of the handle, a nut driver, the second end of the lever pivotally attached to the nut driver, the nut driver for traveling along the lead screw, thereby turning the lead screw, and the lead screw attached to the rotator so that as the lever is depressed by hand the nut driver will travel

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along the lead screw towards the rotator thereby turning the rotator in the process (Figures 3-7). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a first end, a midsection, and a second end, a lead screw, and a nut driver with all the above limitations, as taught by Pratt et al., to Miller since it was known in the art to use lever, screw, and driver mechanisms to advance fastening members from the interior of an applicator to the exterior.

Claim 11: Miller discloses the claimed device except for the lever having a midsection extension.

Pratt et al. teach a lever having a midsection extension **36** (Figure 3). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a midsection extension, as taught by Pratt et al., to Miller since it was known in the art that midsection extensions on levers are used in order to engage with the proximal, driver portion of the applicator.

Claims 12, 13, and 16: Miller discloses the claimed device, except for gear teeth formed within the interior of a handle, a spring loaded pawl pivotally attached to the midsection extension and adapted to engage the gear teeth, the releasable engagement means being a ratchet mechanism.

Pratt et al. teaches gear teeth **48** formed within the interior of a handle, a spring loaded pawl **40** pivotally attached to the midsection extension and adapted to engage the gear teeth, the releasable engagement means being a ratchet mechanism (Figure 3). It would have been obvious to one of ordinary skill in the art to provide the ratchet mechanism including the gear teeth and spring loaded pawl, as taught by Pratt et al., to

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Miller since it was known in the art to use ratchet mechanisms to restrict movement in one direction.

Claims 10 and 15: Miller discloses the claimed device, except for the lead screw being a high helix lead screw. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a high helix lead screw for the lead screw in Miller since it was known in the art that high helix angle thread screws are high efficiency using low rotational speeds.

7. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller** (U.S. Patent No. **4,628,943**) and **Pratt et al.** (U.S. Patent No. **5,607,436**), as applied to Claim 14 above, and further in view of in view of **Knodel et al.** (U.S. Patent No. **5,487,500**).

Claims 17-18: Miller and Pratt et al. disclose the claimed device, including having a mid-section extension and a latch pawl cooperating with the teeth to prohibit the lever from backstroking until it has been completely depressed (see paragraph 7 above), except for a plurality of teeth being formed in the mid-section extension.

Knodel et al. teaches a mid-section extension with formed plurality of teeth (Figure 6). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a plurality of teeth, as taught by Knodel et al., to Miller and Pratt et al. since it was known in the art that teeth are used in ratchet and gear mechanisms which are used in applicators.



***Response to Arguments***

8. Applicant's arguments filed 02/05/2009 have been fully considered but they are not persuasive.

9. The applicant generally argues that Miller fails to disclose the rotator having a longitudinal groove extending along at least a portion thereof. The examiner disagrees. The examiner mentioned that the longitudinal groove is within a distal end **54** of the rotator, which rotates along with a proximal end **44** of the rotator, and holds the proximal end of a helical fastener **62**, as clarified in the annotated figure 2 above. In order to be mounted onto the distal end **54**, there must be a groove that accepts the fastener **62**, which is suggested in figure 2.

***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734